Attorney's Docket No.: 14184-039001 / MIC-008UTL



ITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mark G. Currie et al.

Art Unit : Unknown

Serial No.: 10/766,735

Examiner: Unknown

Filed

: January 28, 2004

Title

: METHODS AND COMPOSITIONS FOR THE TREATMENT OF

GASTROINTESTINAL DISORDERS

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the attached form PTO-1449. Only copies of the non-U.S. Patent publications are enclosed.

This statement is being filed before the receipt of a first Office Action on the merits. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

mita L. Meildejohn, Ph.D.

No. 35/283

Fish & Richardson P.C. 225 Franklin Street Boston, MA 02110-2804 Telephone: (617) 542-5070 Facsimile: (617) 542-8906

20984240.doc

CERTIFICATE OF MAILING BY FIRST CLASS MAIL

I hereby certify under 37 CFR §1.8(a) that this correspondence is being deposited with the United States Postal Service as first class mail with sufficient postage on the date indicated below and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date of Deposi

Signature

Typed or Printed Name of Person Signing Certificate

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Tradeniar Office	Attorney's Docket No. 14184-039001	Application No. 10/766,735
Information Disc by Ap			
(Use several she (37 CFR §1.98(b))	eets II necessary)	Filing Date January 28, 2004	Group Art Unit
	MADEM D'A		

	U.S. Patent Documents						
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	5,395,490	3/7/1995	Hoff	204	132	
	AB	5,140,102	8/18/1992	Currie	530	326	
	AC						

	Foreign Patent Documents or Published Foreign Patent Applications							
Examiner	Desig.	Document	Publication	Country or			Trans	slation
Initial	ID	Number	Date	Patent Office	Class	Subclass	Yes	No
	AD							

	Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner	Desig.		
Initial	ID	Document	
		Amarante et al., "The κ-opioid agonist (±)-bremazocine elicits peripheral antinociception by	
	AE	activation of the L-arginine/nitric oxide/cyclic GMP pathway" European Journal of Pharmacology,	
		Vol. 454: pages 19-23 (2002).	
	AF	Arita et al., "Purification and characterization of a heat-stable enterotoxin of Vibrio mimicus" FEMS	
	111	Microbiology Letters, Vol. 79/1: pages 105-110 (1991).	
		Chan et al., "Amino Acid Sequence of Heat-stable Enterotoxin Produced by Escherichia coli	
	AG	Pathogenic for Man" The Journal of Biological Chemistry, Vol. 256, No. 15: pages 7744-7746	
		(1981).	
	AH	Forte et al., "Lymphoguanylin: Cloning and Characterization of a Unique Member of the Guanylin	
		Peptide Family" Endocrinology, Vol. 140, No. 4: pages 1800-1806 (1999).	
•		Giannela, "Escherichia coli heat-stable enterotoxins, guanylins, and their receptors: What are they	
	AI	and what do they do?" The Journal of Laboratory and Clinical Medicine, Vol. 125, No. 2: pages	
		173-181 (1995).	
	AJ	Gualillo et al., "Ghrelin, a widespread hormone: insights into molecular and cellular regulation of its	
		expression and mechanism of action" FEBS Letters, Vol. 552: pages 105-109 (2003).	
	4 77	Guarino et al., "Citrobacter freundii Produces an 18-Amino-Acid Heat-Stable Enterotoxin Identical	
	AK	to the 18-Amino-Acid Escherichia coli Heat-Stable Enterotoxin (ST Ia)" Infection and Immunity,	
		Vol. 57, No. 2: pages 649-652 (1989).	
	4.7	Huang et al., "Nucleotide sequence of a gene encoding the novel Yersinia enterocolitica heat-stable	
•	AL	enterotoxin that includes a pro-region-like sequence in its mature toxin molecule" Microbial	
		Pathogenesis, Vol. 22: pages 89-97 (1997).	
	AM	Jain et al., "Sildenafil-induced peripheral analgesia and activation of the nitric oxide-cyclic GMP	
		pathway" <u>Brain Research</u> , Vol. 909: pages 170-178 (2001). Kim et al., "Changes in ghrelin and ghrelin receptor expression according to feeding status"	
	AN	NeuroReport, Vol. 14, No. 10: pages 1317-1320 (2003).	
		Lazaro-Ibanez et al., "Participation of the nitric oxide-cyclic GMP-ATP-sensitive K ⁺ channel	
	AO	pathway in the antinociceptive action of ketorolac" <u>European Journal of Pharmacology</u> , Vol. 426:	
	AU	pages 39-44 (2001).	
	_	pages 37-7-1 (2001).	

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no	of in conformance and not considered. Include copy of this form with
next communication to applicant.	

	Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	e e	Attorney's Docket No. 14184-039001	Application No. 10/766,735
	Information Dis by A	closure Statement	3000	Applicant Mark G. Currie et al.	
	(Use several s	heets if necessary)	ر ر مرد	Filing Date January 28, 2004	Group Art Unit
Ì		AUEN			

	Other D	ocuments (include Author, Title, Date, and Place of Publication)
Examiner Initial	Desig. ID	Document
mittal	AP	Moseley et al., "Isolation and Nucleotide Sequence Determination of a Gene Encoding a Heat-Stable Enterotoxin of Escherichia Coli" Infection and Immunity, Vol. 39, No. 3: pages 1167-1174 (1983).
	AQ	Nzegwu et al., "Luminal capsaicin inhibits fluid secretion induced by exterotoxin <i>E. coli</i> STa, but not by carbachol, <i>in vivo</i> in rat small and large intestines" Experimental Physiology, Vol. 81, No. 2: pages 313-315 (1996).
	AR	Rolfe et al., "Enterotoxin <i>Escherichia coli</i> STa activates a nitric oxide-dependent myenteric plexus secretory reflex in the rat ileum" <u>The Journal of Physiology</u> , Vol. 475, No. 3: pages 531-537 (1994).
	AS	Rolfe et al., "Vagotomy inhibits the jejunal fluid secretion activated by luminal ileal Escherichia coli STa in the rat in vivo" GUT, Vol. 44: pages 615-619 (1999).
	AT	Shailubhai, "Therapeutic applications of guanylate cyclase-C receptor agonists" <u>Drug Discovery & Development</u> , Vol. 5 No. 2: pages 261-268 (2002).
	AU	So et al., "Nucleotide Sequence of the Bacterial Transposon Tn1681 Encoding a Heat-Stable (ST) Toxin and Its Identification in Enterotoxigenic Escherichia coli Strains" Proceedings of the National Academy of Sciences of the U.S.A., Vol. 77, No. 7 [Part 2: Biological Sciences]: pages 4011-4015 (1980).
	AV	Soares, et al., "Dibutyryl-cyclic GMP induces peripheral antinociception via activation of ATP-sensitive K ⁺ channels in the RAT PGE ₂ -induced hyperalgesic paw" <u>British Journal of Pharmacology</u> , Vol. 134: pages 127-131 (2001).
	AW	Takao et al., "Amino acid sequence of heat-stable enterotoxin produced by Vibrio cholerae non-01" FEBS), Vol. 193, number 2: pages 250-254 (1985).
	AX	Takao et al., "Isolation, primary structure and synthesis of heat-stable enterotoxin produced by Yersinia enterocolitica" European Journal of Biochemistry, Vol. 152, No. 1: pages 199-206 (1985).
	AY	Vaandrager et al., "Structure and function of the heat-stable enterotoxin receptor/guanylyl cyclase C" Molecular and Cellular Biochemistry, Vol. 230, Nos. 1&2: pages 73-83 (2002).
	AZ	GenBank Accession No. QHECIB; GI:69638; Aimoto et al., June 18, 1999.
	AAA	GenBank Accession No. P01559; GI:123711; So et al., October 25, 2004.
	ABB	GenBank Accession No. AAA24653; GI:147878; Sekizaki et al., April 26, 1993.
	ACC	GenBank Accession No. P01560; GI:123707; Chan et al., June 15, 2004.
	ADD	GenBank Accession No. AAA27561; GI:295439; Ogawa et al., June 12, 1993.
	AEE	GenBank Accession No. P04429; GI:123712; Ogawa et al., June 15, 2004.
	AFF	GenBank Accession No. S34671; GI:421286; Rossolini et al., April 12, 1995.
	AGG	GenBank Accession No. CAA52209; GI:395161; Guglielmetti et al., July 27, 2995.
	АНН	GenBank Accession No. A54534; GI:628844; Arita et al., May 3, 1996.
	AII	GenBank Accession No. AAL02159; GI:15592919; Teixeira et al., September 13, 2001.
-	AJJ	GenBank Accession No. AAA18472; GI:487395; Mikulskis et al., May 26, 1994.
	AKK	GenBank Accession No. S25659; GI:282047; Takao et al., October 15, 1999.

Examiner Signature	Date Considered
EXAMINER: Initials citation considered. Draw line through citation if no next communication to applicant.	ot in conformance and not considered. Include copy of this form with

Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 14184-039001	Application No. 10/766,735
	losure Statement plicant	Applicant Mark G. Currie et al.	
(Use several shot) (37 CFR §1.98(b))	eets if necessary)	Filing Date January 28, 2004	Group Art Unit

	Other Documents (include Author, Title, Date, and Place of Publication)			
Examiner Initial	Desig. ID	Document		
	ALL	GenBank Accession No. P74977; GI:3913874; Ramamurthy et al., June 15, 2004.		
	AMM	GenBank Accession No. BAA23656; GI:2662339; Huang et al., February 13, 1999.		
	ANN	GenBank Accession No. P31518; GI:399947; Ibrahim et al., March 15, 2004.		
	A00	GenBank Accession No. P07965; GI:3915589; Stieglitz et al., June 15, 2004.		
	APP			

Examiner Signature Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.